WHAT IS CLAIMED IS:

1. An immunoassay method useful for determining the presence of TSE protein in a biological sample, comprising the steps of:

a) preparing a relevant biological sample for a Western blot immunoassay;

b) performing the Western blot immunoassay on such sample for TSE protein; and

c) quantitating the TSE protein present

wherein the immunoassay is carried out using a labeled TSE-specific antibody or antibody fragment.

2. The method of claim 1, wherein the labeled TSE-specific antibody or antibody fragment is labeled by covalent linkage to an enzyme.

3. The method of claim 2, wherein the enzyme is selected from the group consisting of alkaline phosphatase, horseradish peroxidase, amylate dehydrogenase, staphylococcal nuclease, δ-5-steroidisomerase, yeast alcohol dehydrogenase, α-glycerophosphate dehydrogenase, triose phosphate isomerase, ribonuclease, urease, catalase, glucose-6-phosphate dehydrogenase, glucoamylase, β-galactosidase, acetylcholinesterase, asparaginase, and glucose oxidase.

4. The method of claim 2, wherein the enzyme is alkaline phosphatase.

5. The method of claim 2, wherein the covalent linkage is accomplished by activation of alkaline phosphatase using sulfosuccinimidyl maleimidomethyl cyclohexane carboxylate.

6. The method of claim 1, wherein the TSE-specific antibody is 3F4 monoclonal antibody or antibody fragment.

7. The method of claim 1 wherein the biological sample is chosen from the group consisting of a homogenized tissue, plasma, and a plasma processing fraction sample.

8. The method of claim 1 wherein the biological sample is prepared by:

a) diluting with a physiologically compatible buffer to form a buffered dilution; and

b) treating the buffered dilution with proteinase-K to form a buffered proteinase-K dilution.

9. The method of claim 8, wherein the biological sample is diluted serially, up to nine logs.

10. The method of claim 8, wherein the physiologically compatible buffer is a buffered saline solution.

11. The method of claim 10, wherein the buffer component of the buffered saline solution is chosen from the group consisting of PBS, 0.1% BSA in PBS, and Tris buffered saline.

12. The method of claim 8, wherein an aliquot of the diluted sample is treated with proteinase-K.

13. The method of claim 12, wherein the proteinase-K treated dilution is concentrated.

14. The method of claim 13, wherein the proteinase-K treated dilution is concentrated by centrifugation or filtration.

15. The method of claim 14, wherein the concentrated proteinase-K treated solution is resuspended and subjected to Western blot immunoassay, comprising the steps of:

a) separating the proteinase-K treated samples electrophoretically;

b) transferring the separated samples to a membrane;

c) adding a blocking agent to the membrane containing the separated samples;

d) incubating the membranes with a labeled antibody or antibody fragment capable of binding to TSE protein;

e) washing the incubated membrane with a low salt buffer to remove any non-binding antibodies and proteins;

f) measuring the signal produced by counting the number of lanes with a detectable signal.

16. The method of claim 15, wherein the Western blot immunoassay utilizes the monoclonal antibody, 3F4, or a fragment thereof as the labeled antibody or antibody fragment for the identification of the TSE protein on the membrane.

17. The method of claim 15, wherein the results of the Western blot are quantified by:

a) determining the number of immunoreactive lanes on the membrane that contain a signal attributable to the presence of pathogen protein; and

b) approximating the amount of pathogen protein present to the limits of detection.

18. An immunoassay method useful for determining the presence of TSE protein in a biological sample, comprising the steps of:

a) diluting the biological sample with a physiologically compatible buffer to form a buffered dilution;

b) treating the buffered dilution with proteinase-K to form a buffered proteinase-K dilution;

c) performing a Western blot immunoassay for TSE protein on the biological sample; and

d) quantitating the TSE protein present,

wherein the immunoassay is carried out using a labeled TSE-specific antibody or antibody fragment.

19. A quantitative Western blot immunoassay method useful for the determination of TSE protein clearance during the processing of plasma products, comprising the steps of:

a) preparing an aliquot of a relevant first sample chosen from plasma or a processed plasma sample for a Western blot immunoassay;

b) performing the Western blot assay for TSE protein on such first sample;

c) quantitating TSE protein in the first sample aliquot;

d) subjecting the first plasma sample or first processed plasma sample to a processing treatment producing a second sample;

e) performing a Western blot assay for TSE protein on an aliquot of the second sample;

f) quantitating TSE protein results in the second sample; and

g) comparing the quantitative TSE protein in the first sample to the quantitative TSE protein in the second sample to determine if the processing step provides detectable TSE protein clearance,

wherein the Western blot assays are carried out using a labeled TSE-specific antibody or antibody fragment.

20. A method of determining TSE protein clearance by a particular plasma processing step:

a) taking a sample of plasma paste prior to the processing step of interest; performing a Western blot analysis on the plasma paste sample to quantitate TSE protein content;

b) spiking the plasma paste with known amount of scrapie brain homogenate; resuspending the spiked paste;

c) taking an aliquot of the resuspended spiked paste; and performing a Western blot analysis on the resuspended spiked paste to quantitate TSE protein content;

d) performing the processing step of interest on the plasma paste thereby obtaining a processed paste and an effluent;

e) taking a sample of the processed paste and performing a Western blot analysis to quantitate TSE protein content in the processed paste; and

f) comparing TSE protein content of the samples tested to determine if satisfactory TSE protein clearance has been obtained,

wherein the Western blot assays are carried out using a labeled TSE-specific antibody or antibody fragment.

21. An immunoassay method useful for determining the presence of TSE protein in a biological sample, comprising the steps of:

a) preparing a relevant biological sample for a Western blot immunoassay;

b) performing the Western blot immunoassay on such sample for TSE protein; and

c) quantitating the TSE protein present

wherein the immunoassay is carried out using a labeled TSE-specific antibody fragment lacking the Fc portion of the antibody.

22. The immunoassay of claim 21, wherein the TSE-specific antibody fragment is the Fab portion of antibody 3F4.